UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOGEN IDEC, INC. SECURITIES LITIGATION	)	CIVIL ACTION NO. 05-10400-WGY

MEMORANDUM

YOUNG, D.J. October 25, 2007

The class action plaintiffs in this action pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act") against defendants Biogen Idec, Inc. ("Biogen"), James C. Mullen ("Mullen"), Burt A. Adelman ("Adelman"), Peter N. Kellogg ("Kellogg"), William H. Rastetter ("Rastetter"), and William Rohn ("Rohn") (collectively, "the defendants"), as well as against individual defendant Thomas Bucknum ("Bucknum"). The defendants and Bucknum each bring a motion to dismiss the plaintiffs' complaint. Both assert that the plaintiffs failed to satisfy the statutorily required heightened pleading standard for claims that allege securities fraud. Bucknum also raises independent arguments for dismissal arising from his participation in a Securities and Exchange Commission ("SEC") settlement agreement.

After carefully reviewing the record and the briefs, and after hearing oral argument on these motions, the Court agreed with

Biogen and Bucknum that the complaint's allegations do not adequately state a claim.

I. FACTUAL AND PROCEDURAL BACKGROUND

Biogen developed, manufactured, and marketed a drug called Tysabri (formerly known as Antegren). Am. Compl. [Doc. No. 77] ¶¶ 4, 68-69. Tysabri was developed in the early 1990s through a collaborative effort that included Dr. Lawrence Steinman and Dr. Ted Yednock. Id. ¶ 64. The primary effect of the drug is to prevent white blood cells from migrating to the brain, which helps to relieve inflammation. Id. ¶ 64. Due to this effect, the drug holds great potential for treating autoimmune diseases such as multiple sclerosis ("MS"), Crohn's Disease ("Crohn's"), and Rheumatoid Arthritis ("RA"). See id. ¶¶ 4, 87. The antipodal and negative consequences of such a medical effect is that the drug could also prevent white blood cells from fighting infections that developed in organs other than the brain. Id. ¶ 64.

One specific concern with inhibited white blood cell defense is the development of Progressive Multifocal Leukoencephalopathy ("PML"). See id. ¶ 61. PML is caused by a polymavirus known as the "JC Virus," which exists in almost all adults due to childhood infection but usually stays latent in one's kidneys and does not invade one's brain unless the immune system is severely impaired. Id. ¶¶ 61-62. PML is one example of an "opportunistic infection"

that occurs "when ordinary benign organisms infect individuals with severely impaired immune systems." See id. ¶ 5 n.2.

Due to the general danger associated with experimental drugs, the Federal Drug Administration ("FDA") requires a tiered and iterative testing procedure before a drug may be marketed and commercially sold in the United States. Id. ¶ 80. The FDA regulations first require testing on animals. Id. The regulations then require three phases of human testing, each iterative phase resulting in more stringent and broader testing and evaluation. Id. ¶¶ 80-81.

On August 17, 2000, Biogen and an additional company, Elan, announced through a joint press release that an agreement had been reached to bring Tysabri to the commercial market. Id. ¶ 68. The agreement required Biogen and Elan to share with each other any positive or negative results observed during testing. Id. ¶ 70. A Joint Project Team and a Joint Commercialization Team were implemented to develop and market the drug for the two companies. Id.

Pre-clinical animal studies began in the early 1990s. Id. ¶¶ 87, 101. The animal studies showed numerous, unexplained deaths. Id. ¶ 103. In an earlier animal study, Dr. Steinman concluded that a possible reason for the deaths was suppression of white blood cell migration. Id. ¶ 104. In April 2001, Dr. Stephen Miller co-authored an article with a Biogen scientist and a Biogen

researcher explaining that the results of the animal studies raised concerns that the drug could be problematic in treating "established autoimmune diseases such as MS." Id. ¶ 109. Dr. Miller recommended to senior Biogen officials that further studies on animals were needed before testing on humans. Id. ¶ 111. Despite Dr. Miller's concerns, Biogen moved into human testing. See id. ¶ 102.

Under the collaboration agreement, both Biogen and Elan conducted clinical trials. Id. ¶ 82. Although both companies were jointly responsible for the trials and were required to communicate the results to each other, Biogen took primary responsibility for the MS trials while Elan took primary responsibility for the Crohn's and RA trials. Id.

Phase I of the human clinical MS trials was completed in December of 1995. Id. ¶ 87. Phase II testing began and had provided promising data by September 2001. See id. ¶ 88. Phase III of the MS testing began in December 2001 with two trials: AFFIRM and SENTINEL. Id. ¶ 89. AFFIRM sought to test the drug's effect on slowing the rate of disability in MS patients. Id. SENTINEL sought to evaluate the safety of Tysabri in combination with Biogen's other MS drug. Id.

Phase III of the Crohn's testing also began in December 2001. Id. ¶ 91. The Crohn's testing likewise consisted of two trials: ENACT-1, which sought to evaluate the ability of Tysabri to induce

remission of the disease, and ENACT-2, which sought to evaluate the duration and effects of the drug. Id.

Phase II of the RA trials began during mid-2004. Id. ¶ 93. The RA trials never progressed to Phase III.

On May 25, 2004, Biogen announced that it had submitted an application to the FDA for fast-track approval of Tysabri for use in treating people with MS based upon the one year of Phase III clinical data. Id. ¶ 86. "Fast-track" approval is an expedited process for receiving FDA approval and is designed to accelerate the approval of drugs that "address an unmet medical need." Id. ¶ 83.

On November 23, 2004, Biogen announced that the FDA had granted accelerated approval of the drug. Id. ¶ 86. The application for and subsequent fast-track approval of Tysabri contributed to a substantial increase in the price of Biogen common stock between February 18, 2004 and February 28, 2005 (the "Class Period"). See id. ¶¶ 3, 170, 175.

Three months later, on February 28, 2005, Biogen suspended all of its Tysabri clinical trials and withdrew the drug from the market. Id. ¶¶ 7, 94. As of this date, Phase III of the AFFIRM MS trial was completed and Phase III of the SENTINEL study was substantially completed; two Phase III studies of the Crohn's trials were completed and a supplemental Phase III trial was in progress; and Phase II of the RA clinical trials had been underway

for approximately eight months. Id. ¶ 94. Biogen withdrew Tysabri from the market because two patients participating in the MS trials had contracted PML, one of which had died. Id. ¶ 7. Additionally, on March 1, 2005, Biogen revealed that a third patient who had participated in the Crohn's trials had died from PML but had purportedly been misdiagnosed with a type of brain cancer. Id.

After the announcement that Biogen would withdraw Tysabri from the market, the common stock price fell $28.63, constituting a 42.5% decline on trading volume of 118,000,000 shares. Id. ¶ 330.

The FDA held an Advisory Committee Hearing on March 7-8, 2006 to determine whether Tysabri should be returned to the market. Id. ¶¶ 8, 132. At the hearing, Biogen discussed two patients who contracted PML in the MS trials and stated that at least one had exhibited signs of the infection as early as November of 2004. Id. ¶¶ 8, 133.

On June 5, 2006, the FDA announced that it had approved the return of Tysabri to the market, but only as a drug of last resort and with a "black-box" warning. Id. ¶ 17. A "black-box" warning is the strictest FDA warning that the agency employs. Id.

On March 2, 2005, the plaintiffs, led by the institutional plaintiffs, filed this class action against all of the named defendants.[1] The class consisted of investors who purchased Biogen

[1] The individual named defendants all held executive-level positions at Biogen, which in turn is a public company that trades its common stock on the NASDAQ stock exchange. Am. Compl.

common stock during the Class Period. Id. ¶¶ 3, 24-30. The complaint alleges that the defendants, with the exception of Bucknum, violated sections 10(b) and 20(a) of the Exchange Act (Counts I & II) and that all of the defendants, including Bucknum, violated section 20A of the Exchange Act (Count III).

The plaintiffs allege that the defendants and Bucknum violated the Exchange Act through material misrepresentations concerning the safety and marketability of Tysabri. Id. ¶ 4. Additionally, the plaintiffs allege that each of the individual defendants, with the exception of Kellogg, sold significant stock holdings while the share value was knowingly inflated.[2] Id. ¶¶ 323, 384. As evidence

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¶ 31. Specifically, at all times relevant to the complaint, Rastetter was Biogen's Executive Chairman and a Director. Id. ¶ 33. Mullen was Biogen's Chief Executive Officer and President. Id. ¶¶ 34. Kellogg was Biogen's Executive Vice President of Finance and Chief Financial Officer. Id. ¶ 35. Rohn was Biogen's Chief Operating Officer. Id. ¶ 36. Adelman was Biogen's Executive Vice President of Development. Id. ¶ 37. Bucknum was Biogen's Executive Vice President and General Counsel from November 2003 until he resigned on March 9, 2005. Id. ¶ 38.

[2] The plaintiffs allege that during the Class Period, Rastetter sold 582,045 shares for total proceeds of approximately $35,000,000, which constituted approximately 78% of the shares he held at the beginning of the Class Period; Mullen sold 192,000 shares for total proceeds of approximately $12,000,000, which constituted virtually all of the shares he held at the beginning of the Class Period; Adelman sold 80,870 shares for total proceeds of approximately $5,000,000, which constituted virtually all of the shares he held at the beginning of the Class Period; Rohn sold 350,000 shares for total proceeds of approximately $20,000,000, which constituted approximately 91% of the shares he held at the beginning of the Class Period; and Bucknum sold 188,600 shares for total proceeds of approximately $12,000,000, which constituted virtually all of the shares he held at the beginning of the Class Period. Am. Compl. ¶¶ 387-392.

of this alleged insider trading, the plaintiffs note that the Securities and Exchange Commission ("SEC") filed an enforcement action against Bucknum. Id. ¶ 340. The SEC and Bucknum settled the action, with Bucknum agreeing to pay $3,000,000 in disgorgement and prohibiting him from serving as an officer or director of a public company for five years. Id. This action led to Bucknum's resignation. See id.

On November 15, 2006, the defendants filed a motion to dismiss the amended complaint. Defs. Mot. to Dismiss [Doc. No. 82]. Bucknum filed a separate motion to dismiss on January 10, 2007. Bucknum Mot. to Dismiss [Doc. No. 96]. This case, with these pending motions, was reassigned to this Court on May 9, 2007. This Court held oral argument on the motions to dismiss on September 11, 2007 and took the matter under advisement, issuing its order of dismissal on September 14 [Doc. 111]. This memorandum sets forth the analysis undergirding the Court's decision.

II. DISCUSSION

A. Standard of Review

The standard of review for a motion to dismiss does not change simply because a heightened pleading standard is imposed. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002). A court must still draw all reasonable inferences from the allegations of the complaint in favor of the plaintiff. Id. While doing so, the court must, at the same time, address whether the

heightened pleading standard is satisfied. Id. Courts must consider the complaint in its entirety, including other documents properly incorporated into the complaint by reference. Tellabs, Inc. v. Makor Issues & Rights, Ltd., -- U.S. -- , 127 S. Ct. 2499, 2509 (2007).

B. Heightened Pleading Standard for Section 10(b) Securities Fraud Claims

To state a claim for securities fraud under section 10(b), a plaintiff must allege that: (1) the defendant "made a materially false or misleading statement or failed to state a fact necessary to make a statement not misleading"; (2) "in connection with the purchase or sale of a security"; (3) "with the intent to deceive, manipulate, or defraud"; and (4) the defendant "was injured by his reasonable reliance" on the misrepresentations. Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007).

In addition, a plaintiff must satisfy the heightened pleading requirements for fraud under Federal Rule of Civil Procedure 9(b) and, more specifically and more stringently, the statutorily heightened pleading standards of the Private Securities Litigation Reform Act ("PSLRA"). Greebel v. FTP Software, Inc., 194 F.3d 185, 193 (1st Cir. 1999) (noting effect of PSLRA is to embody "at least" the standards of Rule 9(b)).

The PSLRA provides two important heightened pleading requirements. First, when a complaint alleges a misleading statement or omission, the plaintiff must "specify each statement

alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Second, the plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. § 78u-4(b)(2).

In practical application, the first requirement necessitates specificity as to the actual statement asserted to be fraudulent, the identity of the speaker, where and when the statement was made, and why the statement was fraudulent. Fitzer v. Security Dynamics Techs., Inc., 119 F. Supp. 2d 12, 18 (D. Mass. 2000). Pleadings will fail for insufficient specificity if they are merely based on information and belief and do not meet these strict "clarity and basis" requirements. See id.; In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 194-95, 198-99 (1st Cir. 2005). While facts sufficient to show clarity and basis are required, the plaintiffs are not required to "plead evidence." In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 199.

To meet the second heightened pleading requirement of the PSLRA, a plaintiff must plead facts sufficient to raise a strong inference that the defendant acted with scienter. The Supreme Court, in the recent decision in Tellabs, Inc. v. Makor Issues & Rights, Ltd. sought to settle circuit disagreement on the stringency of the "strong inference" of scienter standard. See 127 S. Ct. at 2506. The Supreme Court reaffirmed that a strong

inference of scienter must be determined by the facts taken collectively and not based on whether any individual, isolated allegation meets that standard. Id. at 2509. In determining whether such an inference is "strong," however, the Supreme Court adhered to a strict and stringent standard. See id. at 2510. The determination is comparative and must consider "plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Id. The inference of scienter need not be irrefutable, but the standard asks whether "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. This standard, while settling a circuit split, largely conforms to the preexisting standard in this circuit. See Greebel, 194 F.3d at 197 (holding that "a mere reasonable inference [of scienter] is insufficient to survive a motion to dismiss"); Ezra Charitable Trust v. Tyco Inter., Ltd., 466 F.3d 1, 6 (1st Cir. 2006). Additionally, the Supreme Court failed to address the question of whether the scienter requirement may be satisfied by strong inferences of a high degree of recklessness rather than inferences of actual knowledge. Tellabs, Inc., 127 S. Ct. at 2507 n.3. As such, this circuit's practice of allowing a high degree of recklessness to satisfy the scienter standard remains controlling. See Aldridge, 284 F.3d at 82; Greebel, 194 F.3d at 199.

C. The Statements

The plaintiffs allege that the defendants made material, misleading representations in nearly 90 public statements and documented presentations. See, e.g., Am. Compl. ¶¶ 164-67, 176-84, 188-89, 192, 195, 199-205, 209, 213-14, 216, 219-21, 223-25, 230, 232-38, 242, 244, 246, 249-52, 258-64, 268, 271-77, 280-87, 292, 295-99, 301-07, 311-15. The statements alleged as misrepresentations are numerous and largely duplicative. See id. Additionally, the plaintiffs appear to advance a variety of theories as to why the statements are, in fact, fraudulent. The sifting of this morass of statements and theories is aided by a focus on the causation requirement of the PSLRA. The PSLRA requires that "the plaintiff shall have the burden of proving that the act or omission of the defendant . . . caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). This causation requirement necessitates allegations that the plaintiffs were injured through their reasonable reliance on the misrepresentation. Rodriquez-Ortiz, 490 F.3d at 96. Since this is a securities fraud action, the plaintiffs' strongest theory of misrepresentation is that the defendants misrepresented or omitted information relative to the safety of Tysabri that affected the drug's marketability. See Pls. Opp'n Mem. [Doc. 92] at 1, 4-5.

In light of this theory of misrepresentation, the daunting number of alleged fraudulent statements may be synthesized and

represented by the following examples of the plaintiffs' strongest and best supported allegations.

(1) A statement in the February 18, 2004 Press Release attributed to the "Defendants" that states:

> In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. Serious adverse events have included infrequent hypersensitivity-like reactions.

Am. Compl. ¶¶ 164-165.

(2) A statement, article, attributed to Biogen spokesperson Amy Brockelman, in a February 18, 2004 Bloomberg that states:

> Based on our discussion, we believe that one-year data are sufficient for filing.

Am. Compl. ¶ 167.

(3) A statement, attributed to Mullen, in the March 2, 2004 Earnings Release that states:

> Since the completion of our merger late last year, we've had a string of successes in our product pipeline. Furthermore, the past four months of operating as one organization have confirmed the promise of our new company. Biogen Idec is well positioned to achieve our long-term goal of delivering an average of 15 percent top line and 20 percent bottom line growth through 2007.

Am. Compl. ¶ 176.

(4) A March 2, 2004 Conference Call attributed to "each of the Individual Defendants," specifically Mullen and Kellogg, that states:

> Mullen

> [T]he Company was "confident that Biogen Idec is well positioned to achieve our goal of delivering an average of 15% top-line and 20% bottom-line growth through 2007."[3]
>
> Kellogg
>
> The goals that we provided last June for the 4-year average growth rates are also in line. As we laid out, total revenues are targeted to grow 15% on average per year and adjusted EPS is targeted to grow 20% per year on average. If we meet these goals, Biogen Idec should reach a total revenue level of over $3.25 billion and an adjusted EPS above $2.60 in 2007. That's more than doubling our EPS in 4 years.

Am. Compl. ¶ 178.

(5) A statement, attributed to Mullen, during the March 2, 2004 Conference Call that states:

> Now, I want to focus really on the current state of the MS market, I know a lot of people are beginning to think about that very carefully after this announcement two weeks ago. In the US, there is approximately 400 to 450,000 MS patients of which 300 to 350,000 in the relapsing forms, we consider that the eligible market, that market is slightly over half penetrated. That's about 180,000 patients in the US are on one of the interferons or Copaxone. There is more than 50,000 quitters, that number is hard to quantify but we think that's the right ballpark and there is about 10 to 15,000 new patients diagnosed annually. And when you think about the EU marketplace, you can pretty much just double all those numbers except the penetration is a little bit less. So there is huge, there is still a huge unmet need out there. [W]e do believe that this innovative therapy will offer hope to a large number of patients and the market will grow significantly in the US and Europe.[4]

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[3] A similar statement is attributed to Mullen and is included in the March 2, 2004 Earnings Release. Am. Compl. ¶ 176.

[4] A similar comment is attributed specifically to Adelman and a general comment about Biogen growing to become "one of the

Am. Compl. ¶ 180 (alteration in original).

(6) Biogen's Annual Report on Form 10-K[5] attributed to the "Defendants", signed by Mullen, Kellogg, and Rastetter, alleged to contain the same statements as the February 18, 2004 Press Release. Am. Compl. ¶¶ 188, 193.

(7) A March 23, 2004 Press Release attributed to the "Defendants" that states:

> In previous clinical trials, the following adverse events occurred more commonly with natalizumab when compared to placebo: headache, nausea, abdominal pain, infection, urinary tract infection, pharyngitis and rash. Serious adverse events have included infrequent hypersensitivity-like reactions.

Am. Compl. ¶¶ 195, 198.

(8) A statement, attributed to Mullen, in the April 30, 2004 Earnings Report that states:

> We've had an excellent start to the year. Both revenue and earnings results are up strongly. The U.S. filing of ANTEGREN by mid-year is on track. Our recent good news on ANTEGREN's accelerated timeline highlights one of the strategic benefits of the merger. With access to two large scale manufacturing facilities on both coasts, the Company is well-positioned to fulfill ANTEGREN's blockbuster potential.

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world's premier biotech companies" is attributed to Rastetter during the same conference call. See Am. Compl. ¶¶ 181-82. Rohn is also alleged to have commented generally on the good news about the possibility of FDA approval. Id. ¶ 184.

[5] Similarly, the plaintiffs allege that the section 906 certification form for the Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (codified in scattered sections of 11, 15, 18, 28, and 29 U.S.C.), constitutes a misrepresentation. See Am. Compl. ¶ 190. The plaintiffs make the same argument with regard to the issuance of Biogen's Annual Report. Id. ¶ 192.

Am. Compl. ¶¶ 199, 208.

(9) A July 26, 2004 Press Release attributed to the "Defendants" that states:

> To date, approximately 2,800 patients have received natalizumab in clinical trials, and the safety profile continues to support further development. In placebo-controlled trials to date, in both Crohn's disease (CD) and MS, the most commonly reported adverse events in either group were headache, fatigue and nasopharyngitis.

Am. Compl. ¶¶ 230-31.

(10) A statement, attributed to Rohn, in the July 28, 2004 Earnings Release that states:

> We are convinced of Antegren's blockbuster potential . . . . We believe the potential MS market over the next few years will grow to roughly $6 billion, up from $3.6 billion today, and we believe Antegren will not only expand the market but also capture a lion's share of the market.

Am. Compl. ¶ 235.

(11) A statement, attributed to Adelman, during the July 28, 2004 Conference Call that states:

> Antegren will be an important therapy for all patients with MS and obviously for patients currently on therapy who are not experiencing an adequate clinical response.
>
> [T]here is no evidence that Antegren is associated with accelerated disease activation or relapse as we've seen with other potential targeted therapies to lymphocyte trafficking and you know, we have a huge safety database and theses issues have not come up in conversation, you know, with any regulatory authority.

Am. Compl. ¶¶ 237-39.

(12) A statement, attributed to Adelman, in the November 8, 2004 Press Release that states:

> These data [from the Phase III MS trials] demonstrate that natalizumab dramatically reduced the rate of relapses at one year. We believe natalizumab, with its novel mechanism of action, has the potential to be a significant step forward in the treatment of MS.

Am. Compl. ¶¶ 260, 267.

(13) What appears to be a statement made during the February 7, 2005 Conference Call attributed to Adelman that states:

> [R]esults from the SENTINEL trial, as reported in the TYSABRI package insert, demonstrate that TYSABRI added to Avonex® is safe and effective in the treatment of patients with relapsing MS.

Am. Compl. ¶¶ 307, 316.

(14) A February 17, 2005 Press Release not specifically attributed to any individual defendant that states:

> Biogen Idec (NASDAW: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that the Phase III TYSABRI® (natalizumab) AFFIRM monotherapy trial achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of multiple sclerosis (MS). TYSABRI treatment led to a 42 percent reduction in the risk of disability progression relative to placebo. These data also demonstrated a 67 percent reduction in the rate of clinical relapses over two years, which was sustained and consistent with the previously reported one-year results.

Am. Compl. ¶¶ 311-12.

The plaintiffs do not attempt to explain why each individual statement is fraudulent, but internally reference paragraph 172 of the complaint that lists the seven reasons why these statements constitute fraud. See id. ¶ 172. A summary of the seven

enumerated reasons is that once the company and the individuals chose to speak about the success of Tysabri, they had a duty to disclose the inherent risks of the drug's suppression of the immune system, the adverse events that occurred (including the incidents of opportunistic infections), the inadequacy of the testing, and the true nature of the limited marketability of the drug. See id. In addition, specifically related to statement (11), the plaintiffs allege that evidence of exacerbated relapses and rebound diseases existed in a study funded by Elan and published in August 1999 and in a study in 2001 co-authored by a Biogen researcher. See id. ¶¶ 237-39, 245. This pre-existing evidence is alleged to provide further support that statement (11) was fraudulent.

While other statements are alleged as fraudulent by the plaintiffs in the complaint, they merely reassert in other media statements attributed to the defendants as to the market expectations of Tysabri, the centrality of Tysabri to Biogen's future financial success, and representations as to the adverse events shown in clinical reports.[6]

D. Specificity: "Clarity and Basis"

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[6] Excluded from consideration are statements alleged by the plaintiffs that are attributed to persons other than the named defendants and who were not agents or representatives of the corporate defendant Biogen. For example, this includes statements made by the financial community about Biogen. See, e.g., Am. Compl. ¶ 212.

The PSLRA requires the plaintiffs to plead facts sufficient to demonstrate the "clarity and basis" of each alleged misleading statement. In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 194. To meet this standard, the complaint must factually detail the time, place, and content of each statement. Aldridge, 284 F.3d at 78 (citing Greebel, 194 F.3d at 193). The content prong of this standard may be understood as amounting to a requirement that the plaintiff "provide factual support for the claim that the statements or omissions were fraudulent, that is, facts that show exactly why the statements or omissions were misleading." See id.

As the section above demonstrates, the complaint here adequately provides specific information as to time, place, attribution, and content of the actual words associated with each allegedly fraudulent statement. The adequacy of the pled statements are, however, most vulnerable to the latter "content" requirement.

The plaintiffs' theory as to why these statements are fraudulent hinges on the existence of adverse clinical data, specifically indications of PML, about which, it is alleged, the defendants either knew or recklessly failed to learn. See Am. Compl. ¶ 172. The complaint specifically alleges the existence of adverse data. The complaint also specifically alleges statements made by the individual defendants. The complaint is, however, notably deficient as to any specific factual allegations that link

or connect the two. There is not one specific factual averment that alleges when, whether, or how any of the individual defendants learned of this adverse clinical data; thus, there are no factual allegations that any of the defendants knew that their statements were false or fraudulent.

While this lack of factual support arises again in the analysis of scienter, this Court must not conflate the "strong inference" of the scienter requirement in the PSLRA with the general "reasonable inference" standard applicable to the specificity determination. See Aldridge, 284 F.3d at 79 (reversing a district court decision where the judge did not give the plaintiff the benefit of all reasonable inferences when determining specificity). Additionally, the Court must be sure to assume, as it must on all motions to dismiss, that alleged facts are viewed in the light most favorable to the plaintiffs. Tellabs, Inc., 127 S. Ct. at 2509.

When mindful of the reasonable inference standard and after giving the plaintiffs' allegations the benefit of all favorable inferences, the specificity requirement is satisfied. Specific factual allegations exist that the individual defendants made statements as to the specific side-effects that the clinical data had shown, and those enumerated effects do not mention symptoms of PML. The statements also assert that Tysobri will be appropriate for the large majority of patients suffering from MS and not simply

used as a last resort drug. Finally, the statements assert that Tysobri will account for a large portion of Biogen's financial success.[7]

Additionally, the plaintiffs make specific and documented factual allegations that the pre-market clinical data revealed symptoms and incidences of PML. At the specificity prong on this motion to dismiss, this Court must accept those factual allegations as true and assume that the evidence will prove that the clinical data did so contain that adverse data.

Due to the high-level positions of the individual defendants and their willingness and ability to address clinical data in the statements provided, it is a *reasonable* inference that the defendants knew of the adverse data. See Aldridge, 284 F.3d at 79. Such knowledge, if proven, would make the cited statements fraudulent.

E. "Safe Harbor" for Forward-looking Statements

In addition to the specificity and scienter requirements, the PSLRA also carves out a statutory safe-harbor for many "forward-looking" statements. See 15 U.S.C. § 78u-5. "Forward-looking" statements are, generally speaking, statements that speak predictively of future economic performance, plans, and objectives. See id. § 78u-5(i)(1)(A)-(F) (defining

[7] As discussed below, these statements of future financial success implicate, but ought not receive, the limited safe harbor protection for forward-looking statements under the PSLRA.

"forward-looking statement"). Under the safe harbor provisions, fraudulent forward-looking statements cannot give rise to liability in certain circumstances, including those where the statement at issue is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." See 15 U.S.C. § 78u-5(c)(1)(A)(i); In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 195.

Forward-looking statements are often contained in financial filings. See In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 212-13. Congress, in providing the limited safe harbor protection, sought to encourage market efficiency by encouraging companies to disclose future projections without fear that those projections, if they did not materialize, would result in an action for fraud. See H.R. Conf. Rep. No. 104-369, 1995 U.S.C.C.A.N. 730, 742.

When faced with an arguably forward-looking statement, the future projections must be identified and separated from the present facts upon which those projections are based. See In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 212-13. The Court must then consider where the claim of fraud rests. See id. at 213. The statutory protection will only apply where the claim of fraud is based upon the future projection. See id.

In this case, the plaintiffs' allegations of fraud do not solely rest upon the statements of the future earnings or future financial posture of Biogen. The plaintiffs allege, instead, that the fraud occurred with the representation of the present facts, specifically that the clinical data for Tysobri was "clean" and indicated the drug was safe. Under the plaintiffs' theory, it was the failure to disclose the adverse clinical data that constituted the fraud. As a result, none of the statements deserve the statutory protection. See In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 213 ("[W]here the falsehood relates to a representation of present fact in the statement, it will not necessarily come within the statute's safe harbor, even though the statement might also contain a projection of future financial experience."); Veronica H. Montagna, The First Prong of the Safe Harbor Provision of the Private Securities Litigation Reform Act: Can It Still Provide Shelter from the Storm in the Wake of Asher v. Baxter International Inc.?, 58 Rutgers L. Rev. 511, 525 (2006) (explaining safe harbor protection is lost when statement misstates a historical fact).

Additionally, the statutory protection does not apply where the maker of the statement had actual knowledge that it was false or misleading. See Greebel, 194 F.3d at 201. Even if the fraud did rest upon the future financial projections, the plaintiffs here allege that the defendants had actual knowledge of the falsity. If

the plaintiffs' allegations are true, an exception to the statutory protection would apply.

F. Strong Inference of Scienter

While the specificity prong of the PSLRA must be analyzed by giving the plaintiffs all reasonable inferences, the statute changes this standard on a motion to dismiss for failure to state a claim with the second requirement of a "strong inference" of scienter. This determination requires this Court to consider the complaint in its entirety, collectively consider all of the facts alleged, and weigh other plausible opposing inferences. See Tellabs, Inc., 127 S. Ct. at 2509-10. As part of his effort to meet the scienter requirement, a plaintiff may plead motive and opportunity on the part of the defendants along with other factual allegations. Aldridge, 284 F.3d at 82. In the absence of other probative factual allegations, however, "merely pleading motive and opportunity, regardless of the strength of the inferences to be drawn of scienter, is not enough." Greebel, 194 F.3d at 197.

As stated above, the plaintiffs fail to provide even one specific factual allegation that any of the defendants learned of the allegedly adverse clinical data. The strongest support that the plaintiffs provide stems from statements made by Biogen sponsors during the March 7-8, 2006 FDA Advisory Committee Hearings (referred to as "FDA Hearing"; cited as "FDA Tr.") and from various Confidential Sources. At the FDA Hearing, a Biogen sponsor

asserted that PML symptoms began for a 46-year-old woman in November of 2004. The woman died the following February. FDA Tr. at 150-51.

The Biogen sponsors also stated that a second man developed an atypical frontal lesion in October of 2004. Id. at 151. PML was not suspected right away. Id. at 152. PML was suspected, however, months later when behavioral changes occurred and new lesions were found. Id. In February of 2005, the JC virus was detected; its presence confirmed a PML diagnosis. Id.

The Biogen sponsors also detailed a third case of PML involving a man with Crohn's disease who was misdiagnosed with a type of brain tumor called astrocytoma. Id. at 152-54. Retrospective analysis proved that he died instead from PML. Id. at 154. The transcript does not indicate when the retrospective analysis was conducted. See id. at 152-54.

The plaintiffs further allege that six Confidential Sources attest to the defendants' knowledge of the adverse clinical data. See Am. Compl. ¶¶ 143-50. The Confidential Sources allegedly held positions within Biogen at the times relevant to the cause of action or were affiliated with the clinical trials.

Thirdly, the plaintiffs attempt to draw strong inferences from the timing of the completion of different phases of the clinical trials. Specifically, the plaintiffs assert that by January of 2004, the Crohn's trials had ended and Phase II of the MS trials

was completed. See Am. Compl. 143. The inference is that the defendants would have had the analysis of the data from those completed trials at that time. See id.

Finally, the plaintiffs point to the stock sales made by the defendants during the Class Period. See Pls. Opp'n Mem. at 3. The plaintiffs assert that the large amounts of money that the defendants earned from the allegedly inflated stock sales provide a strong inference of scienter due to their motive and opportunity fraudulently to report impending market success. See id.

While the factual support provided by the plaintiffs could support a reasonable inference of knowledge, as described above, it is insufficient to support the drawing of a strong inference of scienter when competing inferences are drawn, considered, and weighed.

First, while the FDA Hearing presentations do review the clinical data and the adverse test results, the transcript of the hearing does not provide any indication as to when the defendants personally learned, if ever, of these clinical results. The FDA Hearing also includes a Biogen sponsor who states that placebo-controlled MS studies demonstrated a similar incidence of infections overall as the actual drug-treated patients. FDA Tr. at 161. It is therefore inconclusive whether the presence of serious opportunistic infections is correctly considered a "red flag" of non-marketability. In addition, even crediting the allegations

that stem from the FDA Hearing, the earliest date of adverse clinical data supported by the transcript occurred in November of 2004.

The plaintiffs' complaint begins to founder at this point. First, the formal, publicly made decision to withdraw Tysobri from the market occurred in February of 2005. The Biogen sponsor at the FDA Hearing stated that the first "symptoms" of PML began to occur in the first woman in November of 2004. FDA Tr. at 150-51. There is no indication of when PML was confirmed or when this information was communicated to any of the defendants. Additionally, the 46-year-old man was confirmed to have the JC virus (and by implication PML) in February of 2005. Id. at 152. The withdrawal of the drug occurred that same month. Id. It is reasonable to infer that the individual defendants, all of whom held high-level executive positions, acted to withdraw Tysabri from the market as soon as they learned of the occurrences of PML. A plausible inference from these facts is that the individual defendants actually learned of the cases of PML on February 18, 2005.[8]

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[8] This inference is supported by the plaintiffs' own memorandum in opposition to Bucknum's motion to dismiss. See Pls. Bucknum Opp'n Mem. [Doc. No. 101] at 2. The plaintiffs state that Bucknum learned at a meeting with other Biogen executives around noon on February 18, 2005 that two patients in the MS trials had PML. Id. Bucknum then proceeded to make the stock trade that was the subject of the SEC enforcement action. Id. These facts, which are argued by the plaintiffs, support an inference that the executives named in this suit actually learned of such adverse data on February 18, 2005, a date that is after that of any alleged fraudulent statement.

Second, the safety data reporting cut-off instituted by the FDA relative to the MS and Crohn's trials was between March 1 and April 30, 2004. Defs. Appx., Ex. 12 at 55. This cut-off date was well before the indications of PML that were allegedly present at the earliest factually supported time of November of 2004. Allegations that Biogen misrepresented data to the FDA or in press releases relative to the FDA approval process may not rest upon clinical data that occurred after that cut-off date.[9]

Finally, if the PML symptoms only began in November of 2004, this undermines the plaintiffs' argument that either the completion of the Crohn's trials or the completion of Phase II of the MS trials necessarily conveyed these adverse safety issues to the defendants because neither was occurring at that time.

The allegations by the Confidential Sources also fail to prove scienter. The Confidential Sources do not allege that any of the defendants knew about the incidences of PML. See Am. Compl. 143-150. They simply allege that adverse events occurred during the trials. See id. These allegations are insufficient for two reasons. First, the proper focus for a determination of scienter

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[9] One of the Crohn's trials patients did die of PML, and the Crohn's trials ended before the cut-off date. The FDA Hearing states, however, that the cause of death was originally misdiagnosed, and there is no indication when the correct diagnosis was actually learned. FDA Tr. 152-154. It is a reasonable inference that the correct diagnosis was learned after the first case of PML was determined in the fall of 2004 and the safety data was reviewed. See id.

in this case is not whether the defendants knew of the presence of any opportunistic infections, but whether they knew of the incidences of PML. The defendants concede that Tysabri patients experienced at least eight opportunistic infections. See Defs. Rev. Mem. in Supp. Mot. to Dismiss [Doc. 86] at 3. The plaintiffs do not demonstrate, however, that the presence of such opportunistic infections affected the market success of Tysabri. The drug was withdrawn based on the presence of PML and not on the presence of any other opportunistic infections.

Second, the allegations purportedly from the Confidential Sources include assertions that Biogen did not report these adverse events to the FDA. See, e.g., Am. Compl. ¶ 147. These allegations, however, are not attributed to or based upon the knowledge of the Confidential Sources but are summaries provided by the plaintiffs. See, e.g., id. Further eroding these conclusory and non-attributed statements regarding the failure to report to the FDA, a review of the publicly available Center for Drug Evaluation and Research Medical Review (dated November 23, 2004), demonstrates significant reporting on adverse events in both the MS and Crohn's trials. See, e.g., Defs. Appx., Ex. 12 at 70-83. The plaintiffs specifically assert in the complaint that one warning sign suggested by a Confidential Source was the development of a melanoma. Am. Compl. ¶ 147. The Medical Review, however, lists clinical data on this subject for the MS trials, with one malignant

melanoma found in the drug-treated patient and two incidences found in the placebo-based patients. Defs. Appx., Ex. 12 at 83. The fact that the FDA approved "fast-track" certification of the drug while in the possession of such data undermines the plaintiffs' reliance on the presence of such adverse events as proof that the drug was unsafe to place on the market. The existence of the exhaustive clinical data disclosures in the Medical Review also undermines the strength of the allegations by the Confidential Sources that the defendants were knowingly or recklessly concealing adverse clinical data.

Finally, the plaintiffs argue that the significant stock sales made by the defendants suggest motive and opportunity to conceal. "Unusual trading or trading at suspicious times or in suspicious amounts by corporate insiders has long been recognized as probative of scienter." Greebel, 194 F.3d at 197. The large percentages of common stock sales by the individual defendants are the plaintiffs most compelling allegations of scienter. The defendants respond that the stock sales were made in conformance with a 10b5-1 trading plan, which undermines the inference of scienter. Defs. Reply [Doc. No. 107] at 12-13.[10]

Valid 10b5-1 trading plans may serve as an affirmative defense to allegations of insider trading. See In re IAC/InterActiveCorp

[10] The defendants supplied those trading plans in the appendix to their memorandum. See Defs. Appx., Exs. 17-20.

Sec. Litig., 478 F. Supp. 2d 574, 604 (S.D.N.Y. 2007). The attempt to use such trading plans as a non-suspicious explanation is undermined, however, when such plans are entered into during the Class Period. See Central Laborers' Pension Fund, Integrated Elec. Servs. Inc., 497 F.3d 546, 554 (5th Cir. 2007). In this case, a review of the SEC Form 4 documents filed pursuant to the 10b5-1 trading plans demonstrates that the plans for Rastetter, Mullen, Adelman, and Rohn were all filed during the Class Period, thus undermining such positive inferences.[11] See Defs. Appx., Exs. 17-20.

Despite the fact that this Court ought not recognize the 10b5-1 trading plans as an affirmative defense to the scienter argument, other plausible inferences must be considered. Here, a purely financial reason for the stock sales is apparent. Tysabri was in its final stages of FDA approval after a decade and a half of testing and held the potential to be a blockbuster drug for serious illness such as MS. The defendants held significant common stock ownership and likely required periodic and incremental sales for tax purposes. Selling stock options while stock prices were increasing, as detailed in the complaint, does present a competing inference of a rational and attractive opportunity for financial gain. A review of the Class Period sales by the defendants, with

[11] The plaintiffs do not assert a section 10(b) cause of action against Bucknum and make no allegations that Kellogg made suspicious common stock trades. See Am. Compl. ¶¶ 384-396.

the exception of Bucknum[12] and Kellogg[13], shows steady and incremental sales throughout the entire period. See Am. Compl. ¶¶ 387-91.

In summary, the quantity and timing of the stock sales present the plaintiffs best support for scienter because they show motive and opportunity to benefit from the alleged fraud. See Aldridge, 284 F.3d at 82. The plaintiffs fail, however, to provide any other factual support that the defendants had knowledge of the indications of PML. Even if inferences of scienter may be drawn from allegations of motive and opportunity, it is not enough to satisfy the PSLRA standard in the absence of other probative factual allegations. Greebel, 194 F.3d at 197.

Instead, in light of the complaint as a whole, the most likely inference is that the defendants learned of the two cases of PML on or about February 18, 2005.[14] No misrepresentations or omissions are alleged to have occurred on or after this date. Thus, the

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[12] Bucknum's stock sales did increase significantly on February 18, 2005, which reflects the insider trading at issue in the SEC enforcement action. See Am. Compl. ¶ 391.

[13] The plaintiffs do not allege that Kellogg made any insider trading stock sales. See Am. Compl. ¶¶ 387-91.

[14] This Court does not make such a determination lightly. This Court is aware of and concerned about the constitutional implications of such a determination. See generally Allan Horwich & Sean Siekkinen, Pleading Reform or Unconstitutional Encroachment? An Analysis of the Seventh Amendment Implications of the Private Securities Litigation Reform Act, 35 No.1 Sec. Reg. L.J. 1 (2007).

plaintiffs fail to allege facts that support a strong inference of scienter.

G. No Predicate Offense Under section 20(a) and 20A

The parties agree that to state a claim for control person liability under section 20(a) and for insider trading under section 20A of the Exchange Act, the plaintiffs must adequately plead a viable predicate violation of the Exchange Act. See Defs. Mem. at 29; Pls. Opp'n Mem. at 29; In re Stone & Webster, Inc., Sec. Litig., 414 F.3d at 193-94.

With regard to Bucknum's motion to dismiss, the parties disagree as to whether the plaintiffs ought be foreclosed outright due to a failure to plead explicitly any predicate offense. See Bucknum Reply [Doc. No. 106] at 5; Pls. Bucknum Opp'n Mem. at 10. The plaintiffs argue that no separate count is required as long as the elements of a predicate offense were adequately pled.[15] Pls. Bucknum Opp'n Mem. at 10. This dispute does not need to be resolved on this motion. Based on the discussion above, even assuming that only the elements of a section 10(b) claim against Bucknum need to be pled, it still fails as a predicate offense because no strong inference of scienter may be found against Bucknum. There is an argument that scienter existed on and after February 18, 2005 when Bucknum learned of the incidences of PML and

[15] There is no dispute that the plaintiffs only allege a section 20A cause of action against Bucknum.

proceeded to make significant stock sales. This argument is of no moment, however, because there are no allegations that Bucknum made any misrepresentations after that date. Thus, with no adequately pled predicate securities violation, the section 20A claim against Bucknum must be dismissed.

As for the other individual defendants, the discussion above demonstrates that the plaintiffs fail adequately to plead a section 10(b) violation. Thus, no predicate securities violation is claimed and the section 20(a) and 20A claims must likewise be dismissed.

III. CONCLUSION

Accordingly, Biogen, Mullen, Adelman, Kellogg, Rastetter, and Rohn's Motion to Dismiss [Doc. No. 82] and Bucknum's Motion to Dismiss [Doc. No. 96] are ALLOWED by this Court by a separate order [Doc. 111].

William G. Young

WILLIAM G. YOUNG
DISTRICT JUDGE